

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 29 MAR 2005



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| Applicant's or agent's file reference<br>2FPO-09-29  | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |                                |
| International application No.<br><b>PCT/KR2002/001839</b>  | International filing date (day/month/year)<br><b>30 SEPTEMBER 2002 (30.09.2002)</b>   | Priority date (day/month/year) |
| International Patent Classification (IPC) or national classification and IPC<br><br><b>IPC7 A61L 27/44</b> |   |                                |
| Applicant<br><br><b>REGEN BIOTECH, INC. et al</b>  |   |                                |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the report
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

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|--|---|
| Date of submission of the demand<br><br><b>04 MARCH 2004 (04.03.2004)</b>  | Date of completion of this report<br><br><b>23 FEBRUARY 2005 (23.02.2005)</b>   |
| Name and mailing address of the IPEA/KR<br> Korean Intellectual Property Office<br>920 Dunsan-dong, Seo-gu, Daejeon 302-701,<br>Republic of Korea<br>Facsimile No. 82-42-472-7140 | Authorized officer<br><br>KIM, Seung Soo<br><br>Telephone No. 82-42-481-5581<br> |

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2002/001839

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

PCT/KR2002/001839

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |            |     |
|-------------------------------|------------|-----|
| Novelty (N)                   | Claims 1-6 | YES |
|                               | Claims     | NO  |
| Inventive step (IS)           | Claims 1-6 | YES |
|                               | Claims     | NO  |
| Industrial applicability (IA) | Claims 1-6 | YES |
|                               | Claims     | NO  |

**2. Citations and explanations (Rule 70.7)**

Reference is made to the following documents:

- D1) US 6030635 A
- D2) US 5958443 A
- D3) US 6326018 B1
- D4) US 5648097 A

**I—Novelty:**

Claim 1 of the present invention is concerned with a bone-filling composition comprising a) 20~80 wt% of mixture containing  $\text{CaSO}_4$ (90~99wt%) and  $\text{CaCO}_3$ ,  $\text{MgCO}_3$ ,  $\text{CaCO}_3\text{?MgCO}_3$ (1~10wt%) and b) 80~20 wt% of viscous biopolymer for stimulating bone-formation and bone-consolidation. Although D1 cited in the international search report discloses malleable paste composition comprising hydrogel carrier and bone powder for filling bone defects, mixture of bone powder is not described in D1. And also, each component of D2-D4 cited in the international search report is different from that of claim 1. Accordingly, the subject matter of claim 1 seems to be novel.(PCT Article 33(2)). Claims 2-6 also comply with PCT Article 33(2) as they are dependent claims.

**II—Inventive step:****1) Concerning claim 1 (Independent claim)**

The references D1-D4 do not disclose the combination of bone powder mixture and viscous biopolymer for stimulating bone-formation and bone consolidation. In addition, it is not obvious from the references D1-D4 by the skilled person in the art. Consequently, there is no suggestion in any of the references, either alone or in combination, which would lead to the solution posed by the present invention. Therefore, claim 1 of the present invention meets the criteria set out in PCT Article 33(3).

**2) Concerning claims 2 to 6 (dependent claims)**

claims 2-6 also comply with PCT Article 33(3) as they are dependent claims.

Claims 1 to 6 meet the criteria set out in PCT Article 33(4), because they are directed to an industrially applicable bone-filling composition for stimulating bone-formation and bone consolidation.